

REMARKS

The Office Action dated August 29, 2007, has been received and carefully considered. In this response claims 1, 2, 6, 8, 9, 11, 12, 16, 17, 19-21, and 23-25 have been amended, and claims 26-30 have been added. No new matter has been added. Entry of the amendments to the claims 1, 2, 6, 8, 9, 11, 12, 16, 17, 19-21, and 23-25, and the addition of claims 26-30 is respectfully requested. Reconsideration of the outstanding rejections in the present application is also respectfully requested based on the following remarks.

I. THE AMENDMENTS TO CLAIMS 1, 11, 19, 24, AND 25

Applicants respectfully submit that amendments to claims 1, 11, 19, 24, and 25 are to more clearly recite the claimed invention. More specifically, the amendments to claims 1, 11, 19, 24, and 25 are to correct grammatical errors, antecedent basis errors or to include claimed limitations that have already been considered by the Examiner. Therefore, the amendments to claims 1, 11, 19, 24, and 25 does not require further consideration by the Examiner and the entry of the amendments to claims 1, 11, 19, 24, and 25 is respectfully requested.

II. THE ANTICIPATION REJECTION OF CLAIMS 1-21 AND 23-25

On page 13 of the Office Action, claims 1-25 were rejected under 35 U.S.C. § 102(e) as being anticipated by Menzie et al. (U.S. Patent No. 6,650,932). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 102, the Patent Office bears the burden of presenting at least a prima facie case of anticipation. In re Sun, 31 USPQ2d 1451, 1453 (Fed. Cir. 1993) (unpublished). Anticipation requires that a prior art reference disclose, either expressly or under the principles of inherency, each and every element of the claimed invention. Id.. "In addition, the prior art reference must be enabling." Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). That is, the prior art reference must sufficiently describe the claimed invention so as to have placed the public in possession of it. In re Donohue, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985). "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." Id..

The Examiner asserts that Menzie et al. discloses the claimed invention. However, Menzie et al. issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15,

2000. Thus, Menzie et al. has an effective filing date of May 15, 2000.

Applicants again respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Applicants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Applicants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Applicants have done) in a declaration, but actual dates of diligence must be provided (which Applicants have provided) (see MPEP 715.07).

In view of the foregoing, Applicants respectfully submit that Menzie et al. is not a proper prior art reference for application against the claims of the present application.

Moreover, regarding claims 1, 11, 19, 24, and 25, the Examiner asserts that Menzie et al. discloses the claimed

invention. However, it is respectfully submitted that Menzie et al. fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising the steps of: "collecting outcomes data sets associated with a medical procedure for a plurality of individuals," as presently claimed. Menzie et al. relates to an individual patient's clinical condition, and a technical device for directly viewing the physiological patient data. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Menzie et al. fails to disclose, or even suggest, "collecting outcomes data sets associated with a medical procedure for a plurality of individuals (e.g., patients)," as recited in independent claims 1, 11, 19, 24 and 25. Rather, Menzie et al. discloses multiple collection devices 132a-n connected to two processing center 140 and 142. The Examiner merely alleges that the "system is able to collect numerous patients/individuals information." However, no support can be found for such allegation in Menzie et al. Furthermore, Menzie et al. discloses a single patient and a single visit or a single clinical episode captured via a single display screen. In contrast, the present application captures

multiple patient visits displayed on multiple display screens. Also, Menzie et al. fails to disclose or even suggest "a medical procedure," as recited in independent claims 1, 11, 19, 24 and 25. Menzie et al. merely discloses that heart rate variability monitors perform signal analysis on physiological signals, and fails to disclose "a medical procedure."

It is also respectfully submitted that Menzie et al. fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising the steps of: "establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the outcomes data sets," as recited in independent claims 1, 11, 19, 24 and 25. Instead, Menzie et al. merely discloses a value of 40 mmHg and fails to disclose or even suggest that the 40 mmHg value is established "based at least in part on an outcomes data group." The Examiner relies on column 7, lines 30-31 of Menzie et al. to disclose "establishing a norm based at least in part on an outcomes data group," as presently claimed. Applicants respectfully submit that the Examiner erred in interpreting the teaching of Menzie et al. In contrast, Menzie et al. discloses "the operator is provided with guidelines for accepting or rejecting the test data." See, e.g., column 7, lines 7-8. Menzie et al. further discloses "the operator may be instructed that substantial

compliance with the desired breathing regimen requires that four of every six breathes fall between the deep breathing maximum value 78 and the deep breathing minimum value 80." See, e.g., column 7, lines 24-28. Therefore, Menzie et al. discloses providing instructions and/or guidelines for the operator to accept or reject the test data and not "establishing a norm based at least in part on an outcomes data group," as presently claimed.

It is further respectfully submitted that Menzie et al. fails to disclose, or even suggest, "comparing a selected one of the at least one outcomes result to the norm," as presently claimed. The Examiner relies on column 6, lines 29-36 and lines 60-67, to disclose such claimed limitation. Instead, Menzie et al. discloses "a breathing performance waveform illustrating parameters of the patient's breathing during the collection of physiological data for each test is displayed on display 36 to the operator of the monitor 14 in order to permit an assessment to be made as to how well the particular test was performed." See, e.g., column 6, lines 21-26. Menzie et al. discloses only accepting the raw physiological data during well-performed testing to improve the accuracy of the test results and not "comparing a selected one of the at least one outcomes result to the norm," as presently claimed. Also, Menzie et al. does not disclose, or even suggest, calculations or comparisons with

other patients, but rather only with one patient. Further, Menzie et al. does not disclose, or even suggest, calculations or comparisons with other medical procedures, but rather only that heart rate variability monitors perform signal analysis on physiological signals. Further, Menzie et al. does not disclose, or even suggest, calculations or comparisons with other organizations, but rather only with one organization at a time. Indeed, Menzie et al. does not disclose, or even suggest, a medical benchmarking system in any manner. In contrast, the present application discloses making benchmark (comparison) calculations across multiple patients for multiple medical procedures for the purpose of comparing multiple organizations. The present application claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator), across any organization (e.g., ambulatory surgery center).

In view of the foregoing, it is respectfully submitted that Menzie et al. fails to disclose, or even suggest, the claimed invention as set forth in claims 1, 11, 19, 24, and 25. Accordingly, it is respectfully submitted that claims 1, 11, 19, 24, and 25 should be allowable over Menzie et al.

Regarding claims 2-10, 12-18, and 20-23, these claims are dependent upon independent claims 1, 11 and 19. Thus, since independent claims 1, 11 and 19 should be allowable as discussed

above, claims 2-10, 12-18, and 20-23 should also be allowable at least by virtue of their dependency on independent claims 1, 11 and 19. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned anticipation rejection of claims 1-25 be withdrawn.

III. THE OBVIOUSNESS REJECTION OF CLAIMS 1-3, 5-13, 15-19, 21-23
AND 25

On page 16 of the Office Action, claims 1-3, 5-13, 15-19 21-23, and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraf et al. (U.S. Patent No. 5,299,119) in view of Seare et al. (U.S. Patent No. 6,223,164). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The Patent Office can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of references. Id. Obviousness cannot be established by combining the teachings of

the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). That is, under 35 U.S.C. § 103, teachings of references can be combined only if there is some suggestion or motivation to do so. Id. However, the motivation cannot come from the applicant's invention itself. In re Oetiker, 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Rather, there must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the art would make the combination. Id.

Kraft et al. fails to teach or suggest a method for collecting and reporting outcomes data for benchmarking ambulatory surgical procedures. Instead, Kraf et al. discloses a device for performing automated calculations for a single patient over time for determining normal or abnormal heart rate variation. Kraf et al. does not disclose, or even suggest, calculations or comparisons with other patients, but rather only with one patient. Also, Kraf et al. does not disclose, or even suggest, calculations or comparisons with other medical procedures, but rather only with one medical procedure. Further, Kraf et al. does not disclose, or even suggest, calculations or comparisons with other organizations, but rather only with one organization at a time. Indeed, Kraf et al. does

not disclose, or even suggest, a medical benchmarking system in any manner. In contrast, the present application discloses making benchmark (comparison) calculations across multiple patients for multiple medical procedures for the purpose of comparing multiple organizations. The present application claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator), across any organization (e.g., ambulatory surgery center).

The Examiner acknowledges that Kraf et al. fails to disclose the claimed feature of "collecting data from a plurality of individuals," recited in independent claims 1, 11, 19, 24 and 25, but asserts that Seare et al. discloses this claimed feature and thus the claimed invention would have been obvious in view of the combination of Kraf et al. and Seare et al. However, Seare et al. is not an analogous art, and thus teaches away from Kraft et al. Specifically, Seare et al. discloses a mechanism for assessing medical service utilization patterns or a mechanism for converting raw medical providers billing data into an information historical database. See column 4, lines 28-36. Kraft et al. on the other hand, discloses a device for performing automated calculations for a single patient over time for determining normal or abnormal heart rate variation. Thus, Seare et al. is not an analogous art to Kraft et al. and one

having ordinary skill in the art would not combine a mechanism for converting billing data into an information historical database with a device for determining normal or abnormal heart rate variation of Kraft et al.

Also, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983). More specifically, Kraft teaches away from collecting data from a plurality of individuals as asserted by the Examiner. Kraft discloses "this automated correlation is unique to this invention and is critical for accurately assessing the extent of autonomic nervous system functioning because the E/I Ratio declines appreciably with age." See, e.g., column 15, lines 24-28. Therefore, Kraft discloses in order to ensure the accuracy of the automated correlation of the data collected for each individual, the data have to be collected singly corresponding to the individual's age. Thus, Kraft teaches away from collecting data from a plurality of individuals as asserted by the Examiner.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-3, 5-13, 15-19, 21-23 and 25 be withdrawn.

IV. THE OBVIOUSNESS REJECTION OF CLAIMS 1-25

On page 20 of the Office Action, claims 1-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brown (U.S. Patent No. 6,101,478) in view of Seare et al. (U.S. Patent No. 6,223,164). This rejection is hereby respectfully traversed.

Regarding claims 1, 11, 19, 24, and 25, the Examiner asserts that Brown substantially discloses the claimed invention. However, it is respectfully submitted that Brown fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking ambulatory surgical procedures comprising the steps of: "collecting outcomes data sets for a plurality of patients," as recited in claims 1, 11, 19, 24 and 25. Instead, Brown discloses "a system for remotely identifying and monitoring a plurality of individuals." See column 3, lines 19-21. In particular, Brown discloses the network system for remotely identifying and monitoring an individual at a time. Thus, Brown fails to disclose or even suggest "collecting outcomes data sets associated with a medical procedure," as recited in claim 1 or "collecting primary source surgical outcomes data sets including a plurality of responses

to a set of indicators for a plurality of patients," as recited in claim 11.

Furthermore, Applicants respectfully submit that Brown fails to disclose or even suggest "establishing a norm based at least in part on an outcomes data groups, the outcomes data group comprising a plurality of the outcomes data set associated with the medical procedure," as recited in claims 1, 11, 19, 24 and 25. The Examiner merely alleges that the norm is the mediums indicated on the graph in Figure 10. However, Brown fails to disclose or even suggest establishing a "norm based at least in part on an outcomes data groups." Furthermore, Brown discloses obtaining a single outcomes data set and not a plurality of outcomes data sets. Thus, Brown fails to disclose or even suggest "establishing a norm based at least in part on an outcomes data group, the outcome data group comprising a plurality of the outcomes data set associated with the medical procedure."

Additionally, the Examiner acknowledges that Brown fails to disclose the claimed feature of "collecting data from a plurality of individuals," recited in independent claims 1, 11, 19, 24 and 25, but asserts that Seare et al. discloses this claimed feature and thus the claimed invention would have been obvious in view of the combination of Brown and Seare et al. However, Seare et al. is not an analogous art, and thus teaches

away from Brown. Specifically, Seare et al. discloses a mechanism for assessing medical service utilization patterns or a mechanism for converting raw medical providers billing data into an information historical database. See column 4, lines 28-36. Brown, on the other hand, discloses a system used to collect data relating to the health status of the patients. The data can be used by healthcare providers or pharmaceutical companies for research or marketing purposes. See column 5, lines 56-60. Thus, Seare et al. is not an analogous art to Brown and one having ordinary skill in the art would not combine a mechanism for converting billing data into an information historical database with a system for collecting data relating to the health status of the patients of Brown.

Also, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-25 be withdrawn.

V. CONCLUSION

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

To the extent necessary, a petition for an extension of time under 37 CFR § 1.136 is hereby made.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

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